Bi cont'd

40. (New) The pharmaceutical composition of claim 36, wherein the long chain alkyl residue is a C_8-C_{24} alkyl residue.

Remarks

Claims

Claims 1-15 have been amended. Claims 16-40 have been added. New claim 16-31 further define the methods of claims 1 to 16. Claim 32-40 are pharmaceutical composition claims directed at unsaturated sphingosides or ceramides which are substantially identical to at least one unsaturated sphingoside or ceramide that is a constituent of a sphingolipid-cholesterol microdomain. Support for these claims can be found on pages 5-7.

Rejection under 35 U.S.C. §101

On pages 2 and 3, the Examiner rejects claims 1-14 under 35 U.S.C. §101 for being in "use claim" format. In particular, the Examiner asserts that the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process.

In response, Applicants have amended the claims to method claims.

Indefiniteness rejections

On pages 3 to 4, the Examiner rejects claims 1-15 under 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In particular, the Examiner rejects the term "derivative" as indefinite wherever it is used in the claims alleging that the identity of the respective derivative would be difficult to ascertain.

The term "derivative" is extensively defined in the specification, in particular on page 5, line 8 to page 7, line 27. Accordingly, the person of ordinary skill in the art would readily understand the meaning of the term derivative and the scope of the rejected claims. Applicants respectfully submits the rejected claims clearly meet the threshold requirements of clarity and precision (MPEP §2173.02).

The Office further rejects claims 1-14 as indefinite for reciting a use without any active, positive steps delimiting how this use is actually practiced.

In response, Applicants have amended the claims to method claims.

The Examiner also rejects in claim 15 the phrase "to a patient at a dose of from 3mg to 30 mg per kg per day." The Examiner alleges that it is not clear what the reference "per kg" refers to. The Examiner states that he interpreted this reference to mean 3mg to 30mg per kg of body weight of the patient per day.

Applicants respectfully submit that the person of ordinary skill, at the time the application was filed, would have understood the reference to "per kg" to mean "per kg body weight" of the patient. Applicants have amended the claims accordingly.

The Examiner also rejects the phrase "characterized in that" as indefinite. The Office alleges that it is unclear whether what follows this phrase is an active step or merely a condition which may be maintained during the process.

Applicants note that the amendments to the claims submitted herewith have eliminated this phrase. Accordingly, the rejection is moot.

Obviousness Rejections

On pages 4 and 5, the Office rejects claim 15 as obvious under 35 U.S.C. §103(a) over U.S. Patent No. 4,551,449 to Ladisch et al.

The Office alleges that it would have be obvious to one skilled in the art at the time the invention was made to administer a cholesterol/ganglioside composition to modulate the cholesterol-lipid microdomain of a cell membrane since Ladisch et al. teach that altering the extracellular amounts of lecithin and/or cholesterol modulate the lipid composition of the cell membrane. The Office further alleges that the person skilled in the art would have known how to determine the dosage limitation recited in the claim.

Ladisch et al seek to avoid the immunosuppressive and antiproliferative effects of lipid emulsions by adding cholesterol to such lipid emulsions. Ladisch et al disclose combinations of triglyceride(s), a phospholipid such a lecithin, glycerol and cholesterol to achieve this goal. Ladisch et al also teach that the lipid composition of cell membranes can be changed by their extracellular environment and that lecithin containing, cholesterol-free emulsions of vegetable oils can withdraw cholesterol from cell membranes, resulting in the inhibition of cell division.

The invention of claim 15 as amended is directed at a method for modulating sphingolipid-cholesterol microdomains in a patient in need thereof.

Applicants respectfully submit that Ladisch et al do not teach such a modulation by the administration of gangliosides, ganglioside derivatives and/or cholesterol

derivatives. Thus, Ladisch et al do not teach or suggest all the claim limitations as required for a prima facie case of obviousness. Furthermore, neither Ladisch et al nor the general knowledge in the art provide motivation to modify Ladisch to arrive at the presently claimed invention nor is there any basis for a reasonable expectation of success.

With respect to the alleged obviousness of the dosage limitation, Applicants submit that the fact that a claim limitation is within the ability of the person skilled in the art is insufficient to establish a prima facie case of obviousness (MPEP §2143.01).

Also, the Office appears to rely in its rejection on "common knowledge in the art" or the personal knowledge of the Examiner to make the suggested modifications to Ladisch et al. Applicants respectfully submit their belief that the knowledge the Office is relying on is not so notorious in character that official notice can be taken. Applicants respectfully request that, if the Office maintains the rejections, they be provided with a reference supporting of the rejection or, if the rejection is based on personal knowledge, to be provided with an Examiner's affidavit.

In the event that this paper is not accompanied by the full fee required for its consideration, the Commissioner is authorized to charge any insufficient or missing fees to RFEM's deposit account No. 02-2135. The Commissioner is also authorized to deposit any overpayment to the same account. A duplicate copy for the financial branch is enclosed.

RESPECTFULLY SUBMITTED,			
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